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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

9

Application Number

10/716,326

Filing Date

November 17, 2003

First Named Inventor

Samuel C. Wadsworth et al.

Art Unit

1646

Examiner Name

Unassigned

Attorney Docket Number

5062CIP

**ENCLOSURES (check all that apply)**☐ Fee Transmittal Form☐ Fee Attached☐ Amendment / Response☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement☐ Certified Copy of Priority Document(s)☐ Response to Missing Parts/  
Incomplete Application☐ Response to Missing  
Parts under 37 CFR  
1.52 or 1.53☐ Assignment Papers  
(for an Application)☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a  
Provisional Application☐ Power of Attorney, Revocation  
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☒ CD, Number of CD(s) 1☐ After Allowance Communication to  
Group☐ Appeal Communication to Board of  
Appeals and Interferences☐ Appeal Communication to Group  
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s)  
(please identify below):**5 pages of PTO-1449; and 43  
publications**

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**Firm  
or  
Individual name

Jennifer D. Tousignant

Signature

Date

April 7, 2004

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

Samuel C. Wadsworth et al.

Examiner: Unassigned

Serial No.: 10/716,326

Group Art Unit: 1646

Filing Date: November 17, 2003

For: **METHODS OF TREATING DIABETES AND OTHER  
BLOOD SUGAR DISORDERS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

CERTIFICATE OF MAILING: Date of Deposit: April 7, 2004

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MICHELE SILVER

Printed name of person mailing correspondence

Michelle Silver

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### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

#### I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- ☒ Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. § § 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- ☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever comes first, and the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for the fee (\$180.00) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 more than three months prior to the filing of this Information Disclosure Statement.

## **II. Copies of the Cited Items:**

- ☒ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are not enclosed:
- ☐ Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. \_\_\_\_\_

filed \_\_\_\_\_ and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).

- ☐ Copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO-1449 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

### III. Concise Explanation of Relevance:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

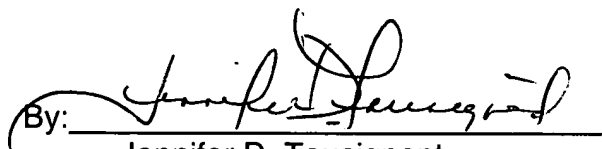
It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. **07-1074** for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

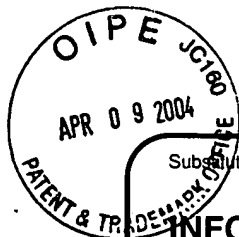
April 7, 2004

Date

By: 

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 5

**Complete if Known**

Application Number	10/716,326
Filing Date	November 17, 2003
First Named Inventor	Samuel C. Wadsworth et al.
Art Unit	1646
Examiner Name	Not Yet Available
Attorney Docket Number	5062CIP

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US-2002/0090719	07-11-2002	Yew	
	2	US- 5,118,666	06-02-1992	Habener	
	3	US- 5,264,618	11-23-1993	Felgner et al.	
	4	US- 5,270,181	12-14-1993	McCoy et al.	
	5	US- 5,283,185	02-01-1994	Epand et al.	
	6	US- 5,334,761	08-02-1994	Gebeyehu et al.	
	7	US- 5,364,771	11-15-1994	Lollar et al.	
	8	US- 5,460,950	10-24-1995	Barr et al.	
	9	US- 5,545,618	08-13-1996	Buckley et al.	
	10	US- 5,563,045	10-08-1996	Pittman et al.	
	11	US- 5,670,488	09-23-1997	Gregory et al.	
	12	US- 5,753,500	05-19-1998	Shenk et al.	
	13	US- 5,856,152	01-05-1999	Wilson et al.	
	14	US- 5,882,877	03-16-1999	Gregory et al.	
	15	US- 5,981,488	11-09-1999	Hoffmann	
	16	US- 5,994,136	11-30-1999	Naldini et al.	
	17	US- 6,013,516	01-11-2000	Verma et al.	
	18	US- 6,191,102	02-20-2001	DiMarchi et al.	
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	19	X WO 95/06743	03-09-95	Dong et al.		
	20	X WO 95/29993	11-09-95	Nabel et al.		
	21	X WO 96/33280	10-24-96	Zhang et al.		
	22	X WO 96/40955	12-19-96	Graham et al.		
	23	X WO 97/00326	01-03-97	Fallaux et al.		
	24	X WO 97/09441	03-13-97	Wadsworth et al.		
	25	X WO 97/25446	07-17-97	Kaleko et al.		
	26	X WO 99/57296	11-11-99	Wadsworth et al.		

Examiner  
SignatureDate  
Considered

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Substitute for form 1449A/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10/716,326	
			Filing Date	November 17, 2003	
			First Named Inventor	Samuel C. Wadsworth et al.	
			Group Art Unit	1646	
			Examiner Name	Not Yet Available	
Sheet	2	of	5	Attorney Docket Number	5062CIP

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	27	ABRUZZESE, Ronald V. et al., Ligand-Dependent Regulation of Plasmid-Based Transgene Expression in Vivo, Human Gene Therapy, Vol. 10, pp. 1499-1507 (June 10, 1999), Mary Ann Liebert, Inc.	
	28	ARGAUD, Doriane et al., Regulation of Rat Liver Glucose-6-Phosphatase Gene Expression in Different Nutritional and Hormonal States, Diabetes, Vol. 45, pp. 1563-1571 (November 1996)	
	29	AYALA, Julio E et al., Conservation of an Insulin Response Unit Between Mouse and Human Glucose-6-Phosphatase Catalytic Subunit Gene Promoters, Diabetes, Vol. 48, pp. 1885-1889 (September 1999)	
	30	BEHR, Jean-Paul et al., Efficient Gene Transfer into Mammalian Primary Endocrine Cells with Lipopolyamine-Coated DNA, Proc. Natl. Acad. Sci., USA, Vol. 86, pp. 6982-6986 (September 1989), Cell Biology	
	31	BOSSELMAN, Robert A., Replication-Defective Chimeric Helper Provirus and Factors Affecting Generation of Competent Virus: Expression of Moloney Murine Leukemia Virus Structural Genes via the Metallothionein Promoter, Molecular and Cellular Biology, pp. 1797-1806 (May 1987), American Society for Microbiology	
	32	CHOW, Billy K.C. et al., Characterization of a Novel Liver-Specific Enhancer in the Human Prothrombin Gene, The Journal of Biological Chemistry, Vol. 266, No. 28, pp. 18927-18933 (October 5, 1991), The American Society for Biochemistry and Molecular Biology, Inc.	
	33	CHRISTENSEN, Mads Tang et al., Glucagon-Like Peptide 1(7-36) Amide's Central Inhibition of Feeding and Peripheral Inhibition of Drinking are Abolished by Neonatal Monosodium Glutamate Treatment, Diabetes, Vol. 47, pp. 530-537 (April 1998)	
	34	CRISTIANO, Richard J. et al., Hepatic Gene Therapy: Efficient Gene Delivery and Expression in Primary Hepatocytes Utilizing a Conjugated Adenovirus-DNA Complex, Proc. Natl. Acad. Sci., USA, Vol. 90, pp. 11552, (December 1993), Genetics	
	35	CURIEL, David T. et al., Adenovirus Enhancement of Transferrin-Polylysine-Mediated Gene Delivery, Proc. Natl. Acad. Sci., USA, Vol. 88, pp. 8850-8854 (October 1991), Biochemistry	
	36	CUIF, Marie-Helene et al., Elements Responsible for Hormonal Control and Tissue Specificity of L-Type Pyruvate Kinase Gene Expression in Transgenic Mice, Molecular and Cellular Biology, pp. 4852-4861 (November 1992), American Society for Microbiology	
	37	DANOS, Olivier et al., Safe and Efficient Generation of Recombinant Retroviruses with Amphotropic and Ecotropic Host Ranges, Proc. Natl. Acad. Sci., USA, Vol. 85, pp. 6460-6464 (September 1988), Genetics	

Examiner Signature		Date Considered	
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
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	38	EMBRETSON, Janet E. et al., Lack of Competition Results in Efficient Packaging of Heterologous Murine Retroviral RNAs and Reticuloendotheliosis Virus Encapsulation-Minus RNAs by the Reticuloendotheliosis Virus Helper Cell Line, <i>Journal of Virology</i> , pp. 2675-2683 (Sep. 1987), American Society for Microbiology	
	39	FEHMANN, Hans-Christoph et al., Insulinotropic Hormone Glucagon-Like Peptide-I(7-37) Stimulation of Proinsulin Gene Expression and Proinsulin Biosynthesis in Insulinoma BetaTC-1 Cells, <i>Endocrinology</i> , Vol. 130, No. 1, pp. 159-166 (1992), The Endocrine Society	
	40	FELGNER, Jiin H. et al., Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations, <i>The Journal of Biological Chemistry</i> , Vol. 269, No. 4, pp. 2550-2561	
	41	FELGNER, Philip L. et al., Lipofection: A Highly Efficient, Lipid-Mediated DNA-Transfection Procedure, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 84, pp. 7413-7417 (November 1987), Biochemistry	
	42	GREGORI, Claudine et al., Characterization of the Aldolase B Intronic Enhancer, <i>The Journal of Biological Chemistry</i> , Vol. 273, No. 39, pp. 25237-25243 (1998) The American Society for Biochemistry and Molecular Biology, Inc.	
	43	GRIMM, Dirk et al., Novel Tools for Production and Purification of Recombinant Adenoassociated Virus Vectors, <i>Human Gene Therapy</i> , Vol. 9, pp. 2745-2760 (December 10, 1998), Mary An Liebert, Inc.	
	44	GOTTSCALK, Stephen et al., Folate Receptor Mediated DNA Delivery into Tumor Cells: Potosomal Disruption Results in Enhanced Gene Expression, <i>Gene Therapy</i> , Vol. 1, pp. 185-191 (1994), Macmillan Press	
	45	GUERRA, MARIA-JOSE M. DIAZ et al., Functional Characterization of the L-Type Pyruvate Kinase Gene Glucose Response Complex, <i>Molecular and Cellular Biology</i> , Vol. 13, No. 12, pp. 7725-7733, American Society for Microbiology	
	46	JUMP, Donald B. et al., Thyroid Hormone and Dietary Carbohydrate Interact to Regulate Rat Liver S14 Gene Transcription and Chromatin Structure, <i>The Journal of Biological Chemistry</i> , Vol. 265, No. 6, pp. 3474-3478 (1990), The American Society for Biochemistry and Molecular Biology, Inc.	
	47	KAYTOR, Elizabeth N. et al., Carbohydrate Regulation of Hepatic Gene Expression, <i>The Journal of Biological Chemistry</i> , Vol. 272, No. 11, pp. 7525-7531 (1997) The American Society for Biochemistry and Molecular Biology, Inc.	
	48	KOCHANNEK, Stefan et al., A New Adenoviral Vector: Replacement of all Viral Coding Sequences with 28 kb of DNA Independently Expressing Both Full-Length Dystrophin and Beta-Galactosidase, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 93, pp. 5731-5736 (June 1996) Medical Sciences	

Examiner Signature	Date Considered
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	49	KUPFER, Joel M., et al., High-Efficiency Gene Transfer to Autologous Rabbit Jugular Vein Grafts Using Adenovirus-Transferrin/Polylysine-DNA Complexes, Human Gene Therapy, Vol. 5, pp. 1437-1443 (December 1994), Mary Ann Liebert, Inc.	
	50	LEE, Hyun Chul et al., Remission in Models of Type 1 Diabetes by Gene Therapy Using a Single-Chain Insulin Analogue, Nature, Vol. 408, pp. 483-488 (November 23, 2000), Macmillan Magazines Ltd.	
	51	LOU, Dan-Qing et al., Chicken Ovalbumin Upstream Promoter-Transcription Factor II, a New Partner of the Glucose Response Element of the L-Type Pyruvate Kinase Gene, Acts as an Inhibitor of the Glucose Response, The Journal of Biological Chemistry, Vol. 274, No. 40, pp. 28385-28394 (1999) The American Society for Biochemistry and Molecular Biology, Inc.	
	52	MARKOWITZ, Dina et al., A Safe Packaging Line for Gene Transfer: Separating Viral Genes on Two Different Plasmids, Journal of Virology, Vol. 62, No. 4, pp. 1120-1124 (Apr. 1988), American Society for Microbiology	
	53	MILLER, A. Dusty, Human Gene Therapy Comes of Age, Nature, Vol. 357, pp. 455-460 (June 11, 1992)	
	54	NAKAYAMA, Kazuhisa, Furin: A Mammalian Subtilisin/Kex2p-like Endoprotease Involved in Processing of a Wide Variety of Precursor Proteins, Biochem. J., Vol. 327, pp. 625-635 (1997) Printed in Great Britain	
	55	O'CALLAGHAN, Brennon L. et al., Glucose Regulation of the Acetyl-CoA Carboxylase Promoter PI in Rat Hepatocytes, The Journal of Biological Chemistry, Vol. 276, No. 19, pp. 16033-16039 (May 11, 2001) The American Society for Biochemistry and Molecular Biology, Inc.	
	56	ROUET, Philippe et al., An Array of Binding Sites for Hepatocyte Nuclear Factor 4 of High and Low Affinities Modulates the Liver-Specific Enhancer for the Human Alpha1-Microglobulin/Bikunin Precursor, Biochem. J., Vol. 334, pp. 577-584 (1998) Printed in Great Britain	
	57	RUFO, Caterina et al., Involvement of a Unique Carbohydrate-Responsive Factor in the Glucose Regulation of Rat Liver Fatty-Acid Synthase Gene Transcription, The Journal of Biological Chemistry, Vol. 276, No. 24, pp. 21969-21975 (2001) The American Society for Biochemistry and Molecular Biology, Inc.	
	58	SABOURIN, Jean-Christophe et al., An Intronic Enhancer Essential for Tissue-Specific Expression of the Aldolase B Transgenes, The Journal of Biological Chemistry, Vol. 271, No. 7, pp. 3469-3473, (February 16, 1996) The American Society for Biochemistry and Molecular Biology, Inc.	
	59	SALVETTI, Anna et al., Factors Influencing Recombinant Adeno-Associated Virus Production, Human Gene Therapy, Vol. 9, pp. 695-706 (March 20, 1998), Mary Ann Liebert, Inc.	

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STATEMENT BY APPLICANT**

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Sheet

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**Complete if Known**

Application Number	10/716,326
Filing Date	November 17, 2003
First Named Inventor	Samuel C. Wadsworth et al.
Group Art Unit	1646
Examiner Name	Not Yet Available
Attorney Docket Number	5062CIP

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	60	THOMPSON, Kimberly et al., Localization of the Carbohydrate Response Element of the Rat L-Type Pyruvate Kinase Gene, The Journal of Biological Chemistry, Vol. 266, No. 14, pp. 8679-8682 (May 15, 1991) The American Society for Biochemistry and Molecular Biology, Inc.	
	61	THULE, PM et al., Regulated Hepatic Insulin Gene Therapy of STZ-Diabetic Rats, Gene Therapy, Vol. 7, pp. 1744-1752 (2000) Macmillan Publishers Ltd.	
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	69	SOUZA, David W. et al., In Vivo Analysis of Muscle Specific Promoter Chimeras, Molecular Therapy, Vol. 5, No. 5, Part 2 of 2 Parts, #1255, S409 (May 2002) The American Society of Gene Therapy	

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